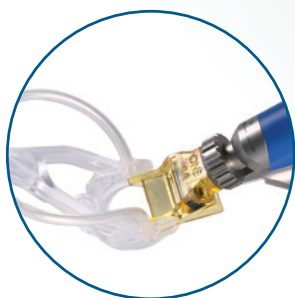


Moria



**A compendium of clinical
and laboratory cases**



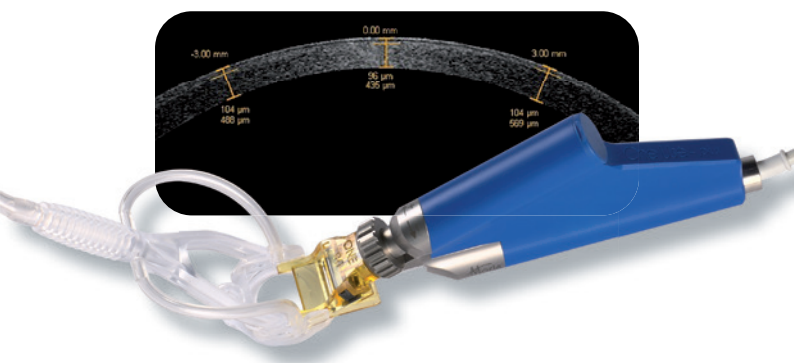
One Use-Plus **SBK**



**Thin planar flaps created predictably
and economically without compromise**

SBK without compromise to reach highly-expected patient satisfaction

One Use-Plus **SBK**



**Flap creation in less than
4 seconds**



**Predictible thin sub-Bowman
flaps**



**Excellent stromal surface
smoothness**



Excellent safety profile



Very fast visual recovery



Excellent quality of vision



**Supported by in-vivo
confocal microscopy**



**Customization of the whole
flap geometry**



One Use-Plus SBK: reliably creates thin planar LASIK flaps

STUDY DESIGN

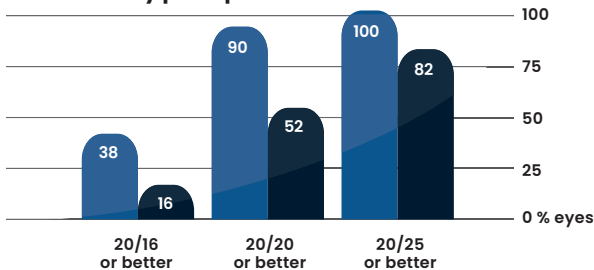
► **Purpose:** To assess outcomes when using One Use-Plus SBK.

► **Participants:** 50 eyes of 25 consecutive myopic patients:

RESULTS

- Flap thickness: **103 ± 9 [83 to 123] μm**
- Vertical flap diameter: **9.3 ± 0.3 mm**
- Pupil tracking successful in 100% of eyes
- **No intraop complications:** no epithelial defects, no epithelial slides
- **No postop complications:** no slipped flaps, microstriae, DLK, or flap complications
- OCT: **planar profile** in all flaps along the horizontal, vertical, and oblique meridia.

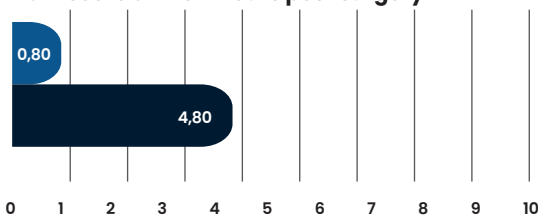
UCVA at 1 day postoperative



■ One Use-Plus SBK - Dr. Duffey (Mobile, AL, USA)¹
 ■ Femto-SBK - Dr. Durrie (Overland Park, KS, USA)*

N=50 N=50

Pain score at 1 to 5 hours post surgery



■ One Use-Plus SBK - Dr. Duffey¹ 0 = no pain
 ■ Femto-SBK - Dr. Duffey* 10 = worst imaginable pain
 N=50 N=50

« The pain occurred at a much lower frequency and intensity with One Use-Plus SBK in the first one to five hours after surgery than with IntraLase SBK. »

Richard J. Duffey, MD

CONCLUSIONS

- One Use-Plus SBK:
- Gentle on epithelium
 - Efficient, accurate and predictable for creation of 100-μm flaps
 - Creates planar flaps
 - Compares favorably to femtosecond lasers.

1. Duffey RJ. Moria One Use-Plus SBK microkeratome: predictably thin, smooth, planar flaps for faster visual recovery. Paper presented during the 26th annual meeting of the ESCRS; Sept 13-17 **2008**; Berlin, Germany.

* **Durrie DS.** From basic science to clinical application: the development of SBK. Presented during the 6th International Congress on Advanced Surface Ablation and SBK; May 5, 2007; Cleveland Clinic, Fort Lauderdale, FL, USA.



Smoother stromal surface than with Femto-LASIK

STUDY DESIGN

► **Purpose:**

To compare quality of flap bed smoothness:

- by Scanning Electron Microscopy (SEM)
- at different magnifications: x20, x40, x80, and x160
- of One Use-Plus SBK vs IntraLase® 60kHz
- targeted to create 100- μ m flaps

► **Design:** Laboratory study

► **Material:** Human corneas not suitable for transplantation

RESULTS

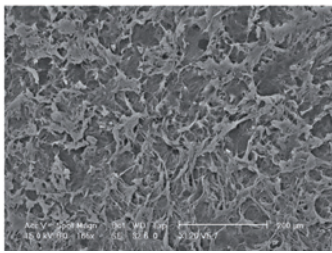
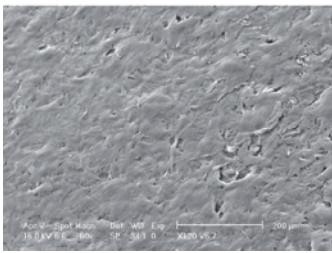
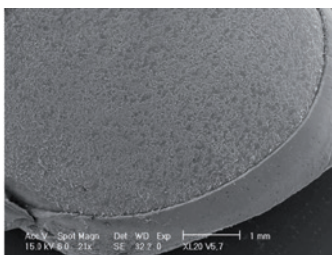
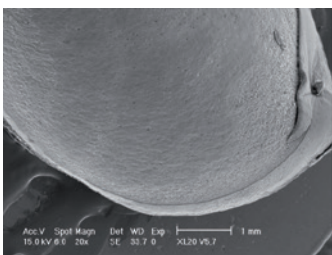
- SEM pictures of intended 100-micron flaps:

Top: 20x magnification

Left: One Use-Plus SBK

Bottom: 160x magnification

Right: IntraLase® 60kHz



One Use-Plus SBK creates a much smoother surface compared to "velcro-like" rough surface when using a FS laser.

« Flap thickness predictability, speed of visual recovery, high order aberrations in custom treated eyes, and smoothness of stromal bed as determined by scanning electron microscopy in eyes undergoing SBK (thin flap LASIK) using the Moria One Use-Plus SBK microkeratome all compare favorably or equally to femtosecond laser SBK flap technology... at a fraction of the cost and with less postoperative pain and potentially fewer postoperative complications. »

Richard J. Duffey, MD

CONCLUSIONS

- One Use-Plus SBK creates smoother, more consistent stromal beds
- Smoother stromal bed ➔ smoother backside surface of the flap ➔ allows a faster healing process for faster visual

I. Duffey RJ. Moria One Use-Plus SBK microkeratome: predictably thin, smooth, planar flaps for faster visual recovery. Paper presented during the 26th annual meeting of the ESCRS; Sept 13-17 **2008**; Berlin, Germany.



Moria SBK vs Alcon FS200

STUDY DESIGN

- ▶ **Design:** Prospective case study
- ▶ **Purpose:** To compare flap performance of Moria SBK vs FS200 (Alcon) when targeting 110- μ m corneal flaps
- ▶ **Materials:**
 - One Use-Plus SBK (Speed 1) vs FS200 (Alcon)
 - both devices were set to create 110- μ m corneal flaps
 - analysis by ultrasound pachymetry
- ▶ **Participants:**
 - 2 matched patient groups presenting similar preoperative characteristics
 - 60 eyes of 30 myopic patients in each group.

RESULTS

	One Use-Plus SBK (Speed 1)	Alcon FS200
Intended central flap thickness (μ m)	110	
OD central flap thickness (μ m)	110.6 \pm 7.4	114.0 \pm 6.6
OS central flap thickness (μ m)	108.2 \pm 6.1	111.4 \pm 7.6
Mean central flap thickness (μ m)	109.4 \pm 6.8	112.7 \pm 7.2
Reproducibility (μ m): OD vs OS	2.4	2.6
Range (μ m): Min - Max	[97 - 125]	[98 - 126]

Proposed formula for Moria SBK flap thickness at Speed 1:

$$\text{Flap thickness} = 67.77 + 0.076 * \text{CCT}$$

CONCLUSIONS

“Both the Alcon Wavelight FS200 femtosecond laser and the Moria SBK microkeratome produced 110- μ m-thick corneal flaps.”

2. Zhang et al. Comparison of corneal flap thickness using a FS200 femtosecond laser and a Moria SBK microkeratome. *Int J Ophthalmol.* **2014**;7(2):273-277.



Moria SBK vs IntraLase® iFS 150kHz

STUDY DESIGN

► **Design:** clinical trial

► **Purpose:** To determine the impact of flap creation methods for SBK on central Bowman's layer thickness

► **Materials:**

- One Use-Plus SBK vs IntraLase® iFS 150kHz (Johnson & Johnson)
- analysis by ultra-high resolution OCT at Day 1-Week 1-Week 2-Month 1 postoperatively

► **Participants:**

- 2 matched patient groups presenting similar preoperative characteristics
- 82 eyes of 41 patients:
 - Moria SBK group: 40 eyes of 20 patients
 - iFS group: 42 eyes of 21 patients

RESULTS

- At each time period after SBK, **flap thickness in the Moria SBK group was significantly thinner** than that in the FS group ($P < 0.05$):
- At 1 month postop, all the eyes had UCVA of 20/20 or better.



CONCLUSIONS

Flap creation by Moria microkeratome and femtosecond laser did not have significantly different impacts on Bowman's layer thickness following SBK.

3. Xu et al. The impact of flap creation methods for Sub-Bowman's Keratomileusis (SBK) on the central thickness of Bowman's layer. PLoS ONE 2015;10(5):e0124996.

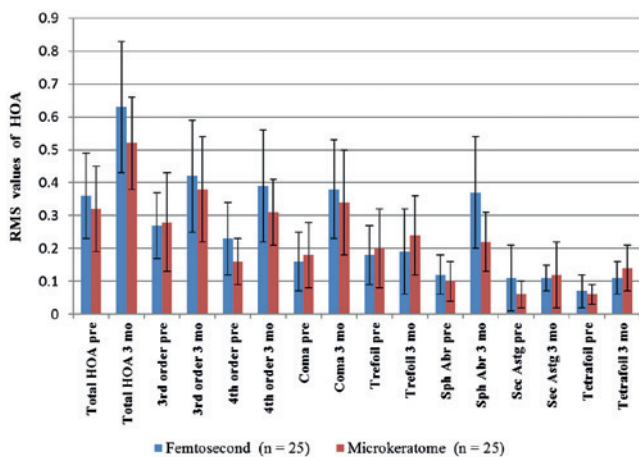
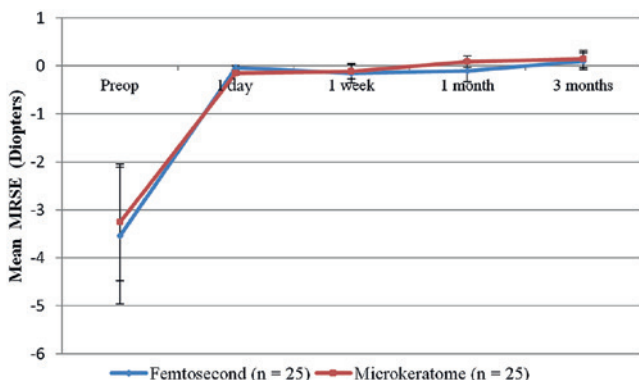


Moria SBK vs IntraLase® iFS 150kHz

STUDY DESIGN

- ▶ **Design:** Prospective comparative clinical trial
- ▶ **Purpose:** To compare the outcomes of wavefront-optimized SBK performed Moria SBK vs IntraLase® iFS 150kHz
- ▶ **Materials:**
 - One Use-Plus SBK vs IntraLase® iFS 150kHz (Johnson & Johnson)
 - Wavefront-Optimized myopic SBK treatment with astigmatism < 2 δ
 - 3-month postoperative follow-up
- ▶ **Participants:**
 - 2 matched patient groups presenting similar preoperative characteristics
 - 50 eyes of 25 patients in each group.

RESULTS



CONCLUSIONS

Flaps created using the Moria One Use-Plus SBK mechanical microkeratome were associated with significantly lower induction of total HOAs and spherical aberrations as compared with 150 kHz iFS flaps at the end of 3 months follow-up.

4. Malhotra et al. Higher Order Aberrations and visual outcomes in Wavefront-Optimized Sub-Bowman Keratomileusis: flap creation using femtosecond laser versus mechanical microkeratome. *Asia Pac J Ophthalmol.* **2015**;4(4):197-203.



Moria SBK & in vivo confocal microscopy

STUDY DESIGN

- ▶ **Design:** prospective case study
- ▶ **Purpose:** To compare the regeneration characteristics of injured corneal subbasal nerve fibers (CSNFs) and keratocyte reaction following LASIK with Moria SBK and LDV femtosecond laser (Ziemer).
- ▶ **Materials & Participants:**
 - Moria SBK group: 32 eyes of 16 myopic patients
 - LDV group: 22 eyes of 11 myopic patients
 - Confocal microscopy using HRTIII® (Heidelberg Eng.) at Month 1,3,6 postoperatively

RESULTS

The central flap thickness examined by in-vivo confocal microscopy was:

	One Use-Plus SBK (Speed 1)	Ziemer LDV
Intended central flap thickness (µm)	110	
Obtained central flap thickness (µm)	108.15	100.59
Accuracy (µm)	1.85	9.41

There was no significant difference between the Moria SBK and Ziemer LDV groups (P>0.05).

	Moria SBK (cells/mm ²)	Ziemer LDV Femto-LASIK (cells/mm ²)
1 Month	118.90 ± 61.73	137.05 ± 67.08*
3 Months	123.37 ± 30.42*	120.93 ± 14.11
*P < 0.05		

The density of stromal keratocytes in the Moria SBK group was higher than that of Femto-LASIK group at 3 months postop (P<0.05).

The repairing velocity of subbasal nerve fibers in the Moria SBK group was a little faster than that of the Femto-LASIK group.

CONCLUSIONS

- "Keratocyte reactions after FS-LASIK and OUP SBK were a little more severe than that after conventional LASIK.
- The repairing velocity of subbasal nerve fibers in the OUP SBK group was a little faster than that of the FS and conventional LASIK groups."

5. Zhang et al. Confocal comparison of corneal nerve regeneration and keratocyte reaction between FS-LASIK, OUP-SBK, and conventional LASIK. Invest Ophthalmol Vis Sci. **2012**;53:5536-5544.

CLINICAL CASE 07



SBK superior to PRK

STUDY DESIGN

► **Design:** prospective case study

► **Purpose:** To compare the outcomes of PRK and thin-flap LASIK/SBK with intended flap thicknesses of 100 µm using the Moria SBK microkeratome.

► **Materials:**

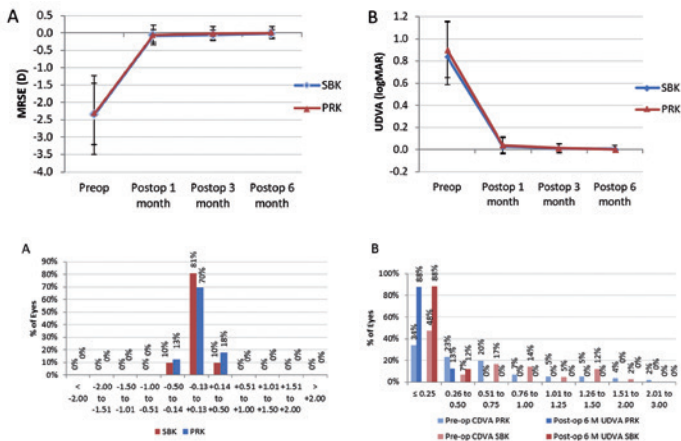
- SBK group: One Use-Plus SBK for 100-µm and 8.5-mm diameter flaps
- PRK group: 8.5-mm ethanol-assisted PRK

► **Participants:**

- 98 eyes of 52 myopic patients:
 - Moria SBK: 42 eyes of 24 myopic patients
 - PRK: 56 eyes of 28 myopic patients

RESULTS

- **Visual & Refractive outcomes:** both MRSE and UDVA showed a statistically significant improvement at postoperative 1, 3 and 6 months from baseline in both SBK and PRK groups:
- **SBK group demonstrated better outcomes:**
 - with 81% of eyes within $\pm 0.13 \delta$,
 - compared to 70% eyes in the PRK group.
- both SBK and PRK group demonstrated similar refractive astigmatism accuracy at postoperative 6 months, with 88% of eyes having cylindrical error < 0.25 D.
- the predictability scatter gram showing attempted versus achieved refractive correction at 6 months also demonstrates **better predictability in the SBK group than the PRK group.**



- **Postop medication:** PRK patients also needed medications for a longer duration (2 months vs. 2 weeks) compared to Moria SBK.

CONCLUSIONS

“The short-term visual and refractive outcomes after both PRK and microkeratome-assisted SBK are comparable at 6 months postop.”

6. Al-Thomali TA. Comparison of microkeratome-assisted SBK with PRK. Saudi J Ophthalmol. 2017;31(1):19-24.



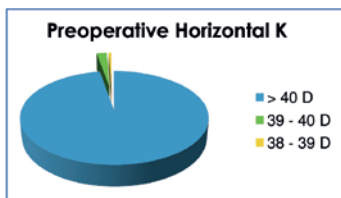
Moria SBK ideal for flat corneas

STUDY DESIGN

- ▶ **Design:** retrospective case study
- ▶ **Purpose:** To evaluate the use of Moria SBK on flat corneas presenting horizontal K < 40 δ.
- ▶ **Materials:**
 - use of Moria SBK with the “-1” metallic suction ring only:
 - 7.5 stop value: 14%
 - 8.0 stop value: 86%
- ▶ **Participants:**
 - 80 eyes of 47 patients:
 - 63 eyes with horizontal K = [39-40] δ
 - 17 eyes with horizontal K = [38-39] δ

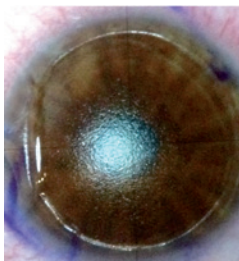
RESULTS:

- ▶ **Safety:**
 - the procedure went uneventfully in all cases: **no complications**
 - the nasal hinge and the stromal bed were normal in size in all cases and sufficient to perform the photoablation laser safely considering:
 - an optical zone between 6.0 and 7.0 mm
 - and transition zone between 1,7 and 1,9 mm



Among 2883 eyes having been treated by Moria SBK:

- 80 eyes (2.77%) had a preoperative Horizontal K < 40 δ
- 63 eyes (2.19%) had a preoperative Horizontal K between [39 - 40] δ
- 17 eyes (0.59%) had a preoperative Horizontal K between [38 - 39] δ



Intraoperative picture of a SBK flap showing the smoothness of the exposed stromal bed on a patient's right eye.

There were no intraoperative nor postoperative complications:

INTRAOPERATIVE		POSTOPERATIVE	
Free cap	0%	Irregular stromal bed	0%
Incomplete flap		DLK	
Buttonhole		Transient light sensitivity: photophobia	
Epithelial erosion		Loss of lines of visual acuity	
Bleeding			
Irregular stromal bed			

CONCLUSIONS

“The Moria One Use-Plus SBK microkeratome is an excellent device that allows the easy creation of thin corneal flaps and regular and smooth corneal beds, safely and predictably even in extremely flat corneas without complications.”

7. **Falcon et al.** Safety of the automated microkeratome for Sub-Bowman's Keratomileusis on the flat cornea. French J Ophthalmol. **2016**;39(2):202-209.



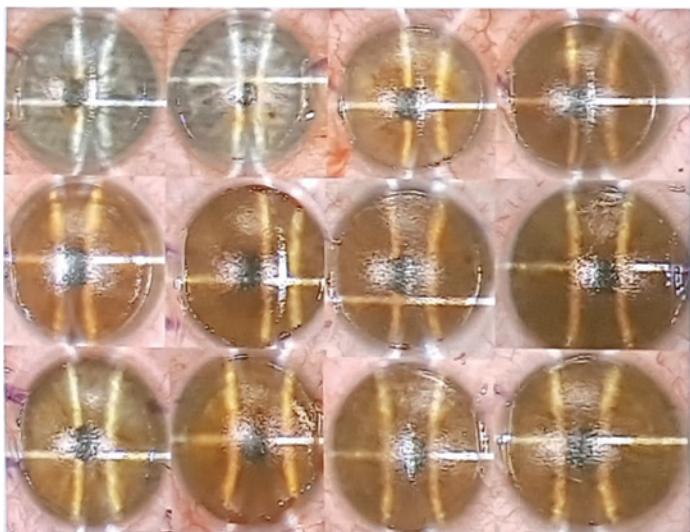
Extra-large flaps ideal for hyperopes

STUDY DESIGN

- ▶ **Design:** retrospective, consecutive, observational case series
- ▶ **Purpose:** To evaluate refractive and visual outcomes of LASIK to treat high hyperopia using:
 - an aberration-neutral profile
 - and a large ablation zone.
- ▶ **Materials:**
 - excimer laser: Amaris 750S (Schwind)
 - One Use-Plus microkeratome with single-use 110- μ m calibrated head
- ▶ **Participants:**
 - 146 consecutive eyes of 77 highly hyperopic patients
 - hyperopia: ranging from +5.25 to +9.5 δ (mean of +6.64 \pm 1.01 δ)
 - 6-month follow-up

RESULTS

- For such large treatment zones, a **LASIK flap size of at least 9.5 mm is a must-have to perform this extreme peripheral photoablation.**
- No single intraoperative flap complication had been noted in that study.



«For large treatment zones, a flap size of at least 10 mm is recommended. To achieve this, we use a microkeratome with a special ring for high hyperopia. Nasal hinge is routinely performed which allows to expose a larger corneal surface compared to the superior hinge. Furthermore, a nasal hinge is also less disturbed by the rolling movements of the eye, more pronounced in hyperopic patients during surgery.»

Laurent Gauthier-Fournet, MD*

CONCLUSIONS

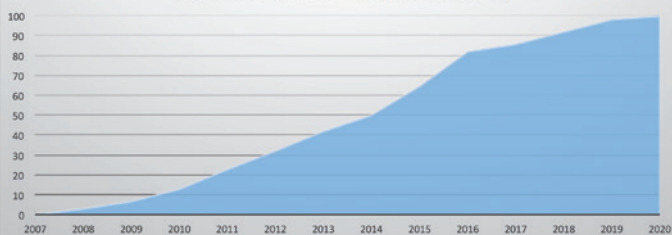
High hyperopia correction with extra-large flaps made possible by using OUP microkeratome should be part of every refractive surgeon's armamentarium.

8. Gauthier-Fournet et al. Six-month outcomes after high hyperopia correction using LASIK with a large ablation zone. *Cornea* **2019**;38(9):1147-1153.

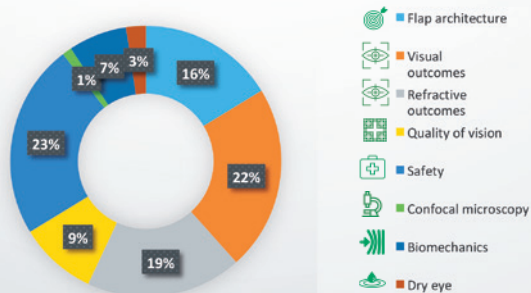
* Gauthier-Fournet L. LASIK for high hyperopia with the Schwind AMARIS. <https://www.eye-tech-solutions.com/en/infocenter/userreports/dr-gauthier-lasik-high-hyperopia-with-schwind-amaris>: Schwind article, September **2016** Accessed on April 17th 2024.

Moria SBK: clinical evidence by graphics

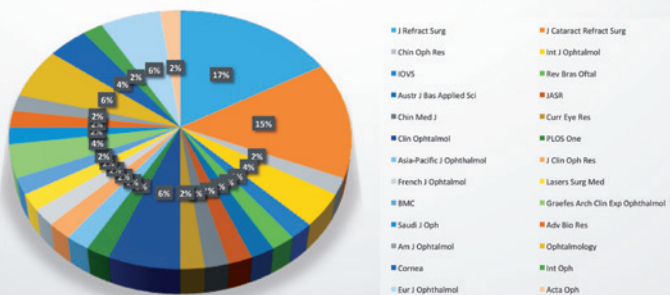
Cumulated %age of publications about OUP (systematic reviews and meta-analysis excluded)



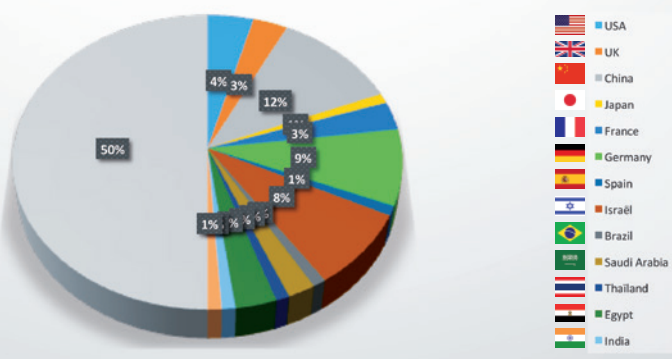
Ratio per clinical purposes

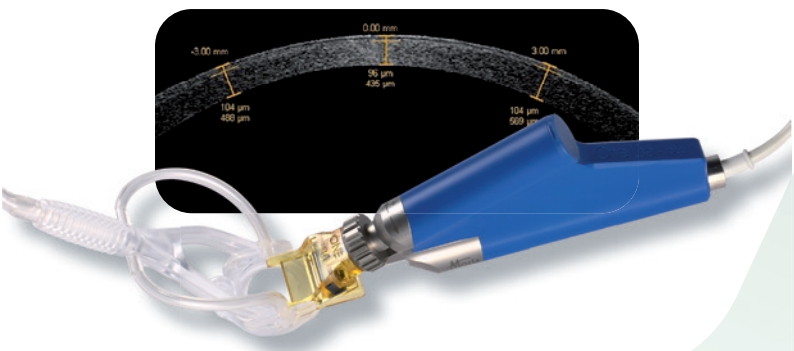


Split per peer-reviewed journal



Split per countries





- Routinely creates planar flaps of approximately 100-microns
- Linear automated microkeratome
- Safety and reliability of 2 independent motors
- Design of suction rings makes the use of a speculum unnecessary on small lid apertures
- Choice of single-use or metallic reusable suction rings
- Translucent single-use suction rings enable visual confirmation of suction
- Adjustable stops for customized hinge length
- Optimal intraoperative visibility
- Reduced suction time, quick procedure
- Much more economical than Femto-LASIK

BIBLIOGRAPHY

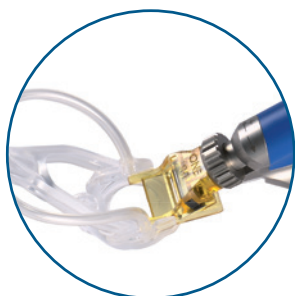
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- Gauthier-Fournet et al.** Six-month outcomes after high hyperopia correction using LASIK with a large ablation zone. *Cornea* **2019**;38(9):1147-1153.

FINANCIAL DISCLOSURE

None of the authors has financial interest in the One Use-Plus SBK microkeratome or is a paid consultant for Moria.

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- One Use-Plus SBK is a product and registered trademark of Moria SA (Antony, France).
- IntraLase® is a product and registered trademark of Johnson & Johnson (USA).
- FS200 is a product and registered trademark of Alcon (Fort Worth, TX, USA).
- LDV® is a product and registered trademark of Ziemer Ophthalmic Systems AG (Port, Switzerland).
- HRTIII® is a product and registered trademark of Heidelberg Engineering (Heidelberg, Germany).
- Amaris 750S is a product and registered trademark of Schwind Eye-Tech-Solutions GmbH (Kleinostheim, Germany).



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